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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,788	07/03/2003	George B. McDonald	8105-009-US-CON	6992

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EXAMINER
OLSON, ERIC

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,788	MCDONALD, GEORGE B.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ~~Sept~~ 28, 2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted August 28, 2006 wherein claim 1 is amended and the specification is amended. This application is a continuation of 09/753814, filed January 3, 2001, now abandoned, which claims benefit of provisional application. 60/233194 filed September 15, 2000.

Claims 1-18 are pending in this application.

Claims 1-18 as amended are examined on the merits herein.

Applicant's substitute oath filed August 28, 2006, has been fully considered and found to be suitable.

Applicant's amendment filed August 28, 2006 with respect to the failure of the specification to reference the priority applications, has been fully considered and found to be persuasive to remove the objection as the specification as amended properly indicates continuity.

Applicant's amendment filed August 28, 2006 with respect to minor informalities in claims 1-18, namely the use of parenthetical expressions, has been fully considered and found to be persuasive to remove the objection to these claims as the amended claims no longer contain parenthetical expressions.

Applicant's amendment filed August 28, 2006 with respect to the rejection of instant claims 1, 2, 7-11, and 16-18 under 35 USC § 112, first paragraph for lacking enablement for the treatment of tissues other than the intestine and liver, has been fully considered and found to be persuasive to remove the rejection as the amended claims are no longer directed to treating disorders of tissues other than the intestine and liver.

Applicant's amendment filed August 28, 2006 necessitates the following new grounds for rejection:

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et. al. (Reference included in PTO-982).

McDonald et. al. teaches that oral administration of the particular topically active corticosteroid, beclomethasone dipropionate (BDP), **alone** in the form of a capsule or **in combination with prednisone** (in the language of instant claim 16) is useful in a method of treating graft-versus-host disease in a human following organ allograft transplantation or stem cell transplantation for 30 days (see abstract and page 28, 1st paragraph, right column). McDonald et. al. also teaches that the subject has damaged

tissue in the intestinal mucosa and liver, in the language of claims 3, 4, and 6 (p. 32, table 4). McDonald et. al. also teaches the effective amount of beclomethasone dipropionate to be administered as 8 mg per day (p. 29, left column, under the heading *Formulation of BDP and Placebo Capsules*), within the range of 4-12 mg/day set by the instant claim 2. McDonald et. al. also discloses that the capsules administered were either uncoated (to dissolve in the stomach) or enteric-coated (to dissolve in the intestine) in the language of instant claim 10(p. 29, left column, under the heading *Formulation of BDP and Placebo Capsules*). McDonald et. al. also reveal the aim for the study therein to compare the effectiveness of oral BDP to that of placebo capsules in the claimed method herein. See abstract and the entire article, especially p. 29, right column, 3rd paragraph. The prior art does not expressly disclose the long-term therapy (i.e., 29-56 days) in the claimed method.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer BDP alone or with prednisone over the long term (i.e. 29-56 days).

One having ordinary skill in the art at the time of the invention would have been motivated to orally administer BDP alone or with prednisone in the long term (i.e. 29-56 days) since the administration of BDP alone or with prednisone for 30 days or les is known according to the prior art, and a subject may not have fully recovered from their condition after 30 days. Thus, one of ordinary skill in the art would reasonably extend the therapy to the longer period from 30 days or less to 56 days if such treatment is still required after 30 days from the beginning of treatment. Moreover, determination of the

time period of administration is considered well within the skill of the artisan, involving merely routine skill in the art.

Thus the invention as a whole is *prima facie* obvious over the prior art.

Response to Argument:

Applicant's arguments and amendment submitted August 28, 2006 have been fully considered and not been found persuasive to remove the rejection of claims 1-10 and 12-17 under 35 USC 103(a).

Applicant argues that the prior art teaches away from long-term (more than 28 days) administration of corticosteroids because of the well-known side effects due to adrenocortical suppression. However, the disclosure of McDonald et al. specifically overcomes this teaching of the prior art by presenting a course of therapy which is sufficiently well tolerated that it could be extended beyond 28 days. McDonald specifically states that the treatment was well-tolerated, and that typical side effects of corticosteroids, such as microbial infections, hypercortisolism, and adrenal insufficiency, were not observed during the treatment. (p. 32, left column, first paragraph, under the heading, "Toxicity from Treatment," and p. 33, left column, last paragraph – right column, first paragraph) In other words, the treatment was finally stopped because of the study design rather than because the patients could not tolerate further treatment. Therefore, given the demonstrated absence of typical corticosteroid-associated side effects from this therapy, one of ordinary skill in the art would have been motivated to extend the duration of treatment beyond the thirty day treatment disclosed by Macdonald et al., and would have reasonably expected success in doing so. While this

treatment would require that patients be monitored closely for the appearance of side effects, such monitoring is well within the ordinary level of skill in the art and is to be expected whenever a patient is being treated with corticosteroids.

Thus Applicant's arguments are not found to be convincing and the rejection is made **FINAL**.

Claims 1-10 and 12-17 are rejected under 35 USC 103(a) as being unpatentable over Baehr et. al. (Included with PTO-892).

Baehr et. al. teaches that oral administration of the particular topically active corticosteroid, beclomethasone dipropionate, alone in the form of a capsule for 28 days, is a useful method of treating graft-versus-host disease in a human following organ allograft transplantation of human leukocyte antigen mismatched marrow. (p. 1233, right column, under the heading, *clinical efficacy*) Baehr et. al. also teaches that, in subjects already taking prednisone, "The prednisone dose at study entry was maintained throughout the study whenever medically possible," (p. 1232. left column, 3rd paragraph) meaning that BDP was administered in conjunction with another prophylactic agent as taught by instant claim 16. Baehr et. al. also teach the use of BDP in subjects who have tissue damage of the intestinal mucosa and liver. Baehr et. al. also teaches the effective amount of beclomethasone dipropionate to be 8 capsules of 1 mg each per day, for a total dose of 8 mg per day, in accordance with instant claim 2. (p. 1232, under the heading, *formulation and dosing of beclomethasone dipropionate*) Baehr et. al. also suggest that the purpose of the study is to evaluate whether the oral BDP is a safe

effective treatment for the instant disease. See the abstract of Baehr et. al. Baehr et. al. does not explicitly disclose the long-term therapy (i.e. 29-56 days) of the claimed invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer BDP alone or with prednisone over the long term (i.e. 29-56 days).

One having ordinary skill in the art at the time of the invention would have been motivated to orally administer BDP alone or with prednisone in the long term (i.e. 29-56 days) since the administration of BDP alone or with prednisone for 30 days or les is known according to the prior art, and a subject may not have fully recovered from their condition after 30 days. Thus, one of ordinary skill in the art would reasonably extend the therapy to the longer period from 30 days or less to 56 days if such treatment is still required after 30 days from the beginning of treatment. Moreover, determination of the time period of administration is considered well within the skill of the artisan, involving merely routine skill in the art.

Thus the invention as a whole is *prima facie* obvious over the prior art.

Response to Argument:

Applicant's arguments and amendment submitted August 28, 2006 have been fully considered and not been found persuasive to remove the rejection of claims 1-10 and 12-17 under 35 USC 103(a).

Applicant argues that the prior art teaches away from long-term (more than 28 days) administration of corticosteroids because of the well-known side effects due to

adrenocortical suppression. However, the disclosure of Baehr et al. specifically overcomes this teaching of the prior art by presenting a course of therapy which is sufficiently well tolerated that it could be extended beyond 28 days. Baehr et al. specifically states that, while a decline in cortisol levels was observed in the patients being treated, this decline did not lead to any clinically significant symptoms suggestive of adrenocorticosteroid excess. (p. 1234, right column) No adverse events were observed which could be related to BDP. (p. 1236, left column, last paragraph – right column, first paragraph) In other words, the treatment was finally stopped because of the study design rather than because the patients could not tolerate further treatment. Therefore, given the demonstrated absence of typical corticosteroid-associated side effects from this therapy, one of ordinary skill in the art would have been motivated to extend the duration of treatment beyond the thirty day treatment disclosed by Baehr et al., and would have reasonably expected success in doing so. While this treatment would require that patients be monitored closely for the appearance of side effects, such monitoring is well within the ordinary level of skill in the art and is to be expected whenever a patient is being treated with corticosteroids.

Thus Applicant's arguments are not found to be convincing and the rejection is made **FINAL**.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et. al. (References supplied with PTO-892) or alternately Baehr et. al. (Reference supplied with PTO-892), in view of, alternately, US patents Lundquist,

Brancq et. al., or Benita et. al. (US patents 5843465, 5958431, and 6007826, all cited in PTO-892).

McDonald et. al. and Baehr et. al. both teach that oral administration of the particular topically active corticosteroid, beclomethasone dipropionate (BDP), is useful in a method of treating graft-versus-host disease in a human following organ allograft transplantation or stem cell transplantation for 30 days. The prior art does not expressly disclose the long-term therapy (i.e., 29-56 days) in the claimed method, or the administration of the active agent as an emulsion

Lundquist, Brancq et. al., and Benita et. al. all disclose pharmaceutical emulsions, and methods for preparing the same from hydrophobic pharmaceutical compounds. (see, for example, claim 1 of Lundquist, claim 1 of Brancq et. al., or claim 1 of Benita et. al.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer BDP alone or with prednisone over the long term (i.e. 29-56 days). It would also have been obvious to prepare the drug as an emulsion, in the manner of claim 11, as disclosed by the aforementioned US patents.

One having ordinary skill in the art at the time of the invention would have been motivated to orally administer BDP in the long term (i.e. 29-56 days) since the administration of BDP alone or with prednisone for 30 days or les is known according to the prior art, and a subject may not have fully recovered from their condition after 30 days. One of ordinary skill in the art would have been motivated to administer the compound as an emulsion to increase solubility and bioavailability. Thus, one of

ordinary skill in the art would reasonably extend the therapy to the longer period from 30 days or less to 56 days if such treatment is still required after 30 days from the beginning of treatment, and to administer the therapeutic agent as an emulsion. Moreover, determination of the time period of administration and optimal dosage formulation is considered well within the skill of the artisan, involving merely routine skill in the art.

Thus the invention as a whole is *prima facie* obvious over the prior art.

Response to Argument:

Applicant's arguments and amendment submitted August 28, 2006 have been fully considered and not been found persuasive to remove the rejection of claim 11 under 35 USC 103(a).

Applicant argues that the prior art teaches away from long-term (more than 28 days) administration of corticosteroids because of the well-known side effects due to adrenocortical suppression. However, as described above the disclosures of McDonald et al. and Baehr et al. specifically correct this defect in the prior art by disclosing that their methods do not lead to significant side effects.

Thus Applicant's arguments are not found to be convincing and the rejection is made **FINAL**.

Claims 1-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Punch et. al. (Included with PTO-892), or alternately Chao (Reference included with PTO-1449), in view of Sequeira et. al. (US patent 6057307, cited in PTO-892).

Punch et. al. teaches that systemically administered corticosteroids are a standard therapy used to reduce the likelihood of rejection in liver transplant recipients, a therapy which is complicated by the presence of multiple side effects including weight gain, hypertension, hyperlipidemia, glucose intolerance, hirsutism, acne, and osteoporosis. (p. 783, first paragraph) The object of the research disclosed by Punch et. al. was an attempt to relieve said side effects by withdrawing corticosteroid treatment 1 year after transplantation.

Chao teaches that, "Corticosteroids are the most widely used "front-line" therapy for the treatment of clinical GVHD [Graft-Versus-Host Disease]. This class of drug has been combined with other immunosuppressants in the prophylaxis against GVHD." (P. 176, under the heading, *Corticosteroids*)

Neither of the aforementioned references explicitly discloses topical administration of corticosteroids in order to treat disease with reduced side effects.

Sequeira et. al. teaches, "A method of treating a corticosteroid-responsive disease of the lower airway passages or lungs, which comprises administering as initial or maintenance therapy to the surfaces of said lower airway passages or lungs, at least once daily, a substantially non-systemically bioavailable amount of aerosolized particles of mometasone furoate effective for treating said disease." (Claim 1) In other words, the invention of Sequeira et. al. comprises a method of locally treating a disease responsive to corticosteroids by administering mometasone furoate in an inhalable form locally to the lungs. Sequeira et. al. also teaches that systemically bioavailable corticosteroids cause unwanted side effects (column 1, lines 51-55), and that a major benefit of the

claimed invention is that mometasone furoate avoids this complication because it does not become systemically bioavailable from the gastrointestinal tract. (Column 3, lines 40-54) Although Sequeira et. al. does not mention host-versus-graft disease due to lung transplantation by name, this condition falls within the claim language of, "a disease responsive to corticosteroids," which would be treatable by, "a substantially non-systemically bioavailable amount of aerosolized particles of mometasone furoate effective for treating said disease."

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Punch et. al. or Chao by administering a topically active corticosteroid such as mometasone furoate to the intestinal tract or liver, in place of or in addition to standard systemic corticosteroid therapy, to a patient suffering from either graft-versus-host or host-versus-graft disease affecting the intestine and/or liver.

One of ordinary skill in the art would have been motivated to modify the invention in this way in order to treat graft-versus host and host-versus-graft disease in the intestine or liver without causing the severe systemic side effects which are observed with existing corticosteroid therapy.

One of ordinary skill in the art would have reasonably expected success because, as taught by Punch et. al. and Chao, existing corticosteroids were therapeutically effective against graft-versus host and host-versus-graft disease to the point that they were in common use despite their substantial side effects, and because mometasone furoate was already known, by Sequeira et. al., to be effective at treating corticosteroid-responsive diseases.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument:

Applicant's arguments and amendment submitted August 28, 2006 have been fully considered and not been found persuasive to remove the rejection of claims 1-16 and 18 under 35 USC 103(a).

Applicant argues that there would be no motivation to apply mometasone furoate to the gastrointestinal tract or liver. However, topical administration to the lings and airways is substantially similar to topical administration to the gastrointestinal surfaces, differing only in the details of pharmaceutical dosage form and route of administration, and a drug which is effectively administered to the lungs by inhalation will be expected to be administered to the gastrointestinal tract by oral administration. In both cases the drug is administered topically to the target cells from outside the body, without becoming systemically absorbed, in order to control inflammation. Although a drug could conceivably be metabolized before reaching the gastrointestinal tract, this is shown not to be the case for other steroids by the discussion of incidental gastrointestinal delivery during inhalation by Sequiera et al. (column 1, lines 37-65) Based on the general state of the art, as demonstrated by Punch et al., Chao, and Sequeira et al., one of ordinary skill in the art would reasonably have expected corticosteroids to be useful for the treatment of inflammatory conditions in any tissue to which they are delivered, whether the tissue in question is the lung, the intestine, or the liver. Therefore one of ordinary skill in the art would have been motivated to administer

mometasone furoate topically to the intestine and liver and would have had a reasonable expectation of success in doing so.

Thus Applicant's arguments are not found to be convincing and the rejection is made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 U.S. Patent No. 6096731 (Cited in PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent 6096731 is drawn to a method for preventing tissue damage associated with graft-versus-host disease having undergone

hematopoietic stem cell transplantation, which is not patentably distinct from the invention claimed by the instant application. The claims of the instant application are drawn to a method of treating a patient requiring long-term therapy following hematopoietic stem cell transplantation having graft-versus-host disease or following organ allograft transplantation having host-versus-graft disease comprising same active agents. One having ordinary skill in the art at the time the invention was made would have been motivated to employ the same active agents in a method of treating a patient requiring long-term therapy following hematopoietic stem cell transplantation having graft-versus-host disease or following organ allograft transplantation having host-versus-graft disease since the same active agents are known to be useful in a method for preventing tissue damage associated with graft-versus-host disease having undergone hematopoietic cell transplantation or intestinal or liver transplantation. Therefore, one of ordinary skill in the art at the time of the invention would reasonably have expected that these active agents would have been beneficial in the instant claimed method.

Response to Argument:

Applicant's arguments and amendment submitted August 28, 2006 have been fully considered and not been found persuasive to remove the rejection of claims 1-18 on grounds of non-statutory double patenting.

Applicant argues that the claimed invention is drawn to a method of long-term treatment while the claimed invention of '731 are drawn to a method of preventing tissue damage. However, the therapeutic goal of preventing tissue damage is a form of

treatment, as it suppresses a symptom of graft-versus-host disease. Furthermore, the actual steps described in claim 1 of '731 consist of administering to the patient a prophylactically effective amount of a topically active corticosteroid for a period of time following allogenic hematopoietic cell transplantation and prior to the presentation of symptoms associated with graft-versus-host disease. The topically active corticosteroid is to be administered for a period of time after the transplantation, and must be continued in order to prevent the development of a graft-versus-host response. Because this is a prophylactic response, administration should begin soon after transplantation, in order to begin therapy before tissue damage has had time to develop. Claim 11 of '731 states that treatment ceases after 80 days following infusion of the hematopoietic cells. Combined with the limitations of base claim 1 of '731, this claim is drawn to a method of treatment lasting for about 80 days, which is much longer than the 28 day limitation which Applicant claims is universally recognized in the prior art.

P. 3, paragraphs 2-3 of the instant specification states that the claimed invention is similarly drawn to a method in which administration of topically active corticosteroid begins following hematapoietic cell transplantation and continues up to day 56 following the transplantation, thereby treating, delaying and/or reducing the severity of the symptoms normally associated with tissue damage caused by GVHD. The window of time during which the topically active corticosteroid is administered is thus similar to that of the instant invention. Both methods begin therapy after transplantation and continue it for a period of time of longer than days.

The new reference, Utiger, cited by Applicant in a supplemental information disclosure statement, is not deemed persuasive to overcome this rejection as it concerns the differences between inhaled and systemically bioavailable oral corticosteroids for the treatment of inflammatory diseases of the lung, rather than comparing inhaled topically active corticosteroids for the treatment of lung disease to oral TACs for the treatment of inflammatory diseases of the gastrointestinal tract and liver.

Thus the claimed invention is not patentably distinct from that of claims 1-40 of '731.

Thus Applicant's arguments are not found to be convincing and the rejection is made **FINAL**.

Summary

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson
Patent Examiner
AU 1623
9/15/06

Anna Jiang
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